

REMARKS

Claims 1 and 3 – 26 are currently pending, with Claims 11 – 25 having been withdrawn from consideration and Claims 1 – 10 examined on the merits. In the Office Action, Claims 1 – 10 were rejected under Section 103 as allegedly obvious from the disclosure in U.S. Patent No. 4,784,173 to Nelson et al. (“Nelson”).¹

Each of the foregoing rejections is respectfully traversed. Favorable reconsideration and allowance of all claims is requested in view of the above amendments and following remarks.

I. The Restriction Requirement.

On March 16, 2010, the Examiner telephoned the Applicant’s attorney to indicate that a restriction was being issued in the case between the following groups of allegedly distinct claims:

Group I	Claims 1-10
Group II	(undefined)
Group III	Claims 11-13
Group IV	Claims 14-15
Group V	Claims 16-23
Group VI	Claims 24-25

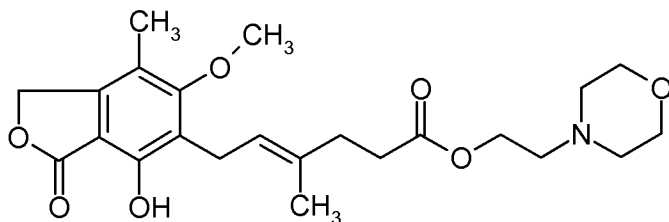
The Examiner has restated the restriction in the written Office Action. In response, the Applicants again provisionally elect Claims 1 – 10 for initial prosecution, with traverse.

II. The Prior Art Rejections.

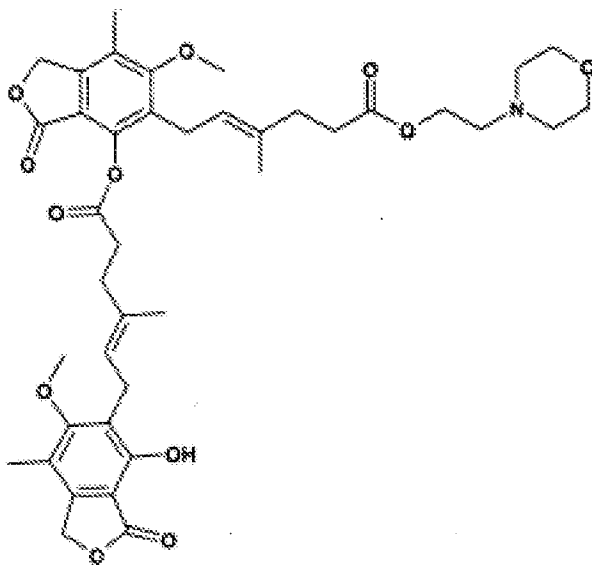
Again, the Examiner argues that Claims 1 – 10 are obvious over the Nelson patent. It is respectfully submitted that these rejections are not well-taken.

Claim 1 has been amended herein to clarify that the claim is directed to a process for the purification of mycophenolate mofetil of formula I (repeated below for convenience) by removing its by-products.

¹ Page 9 of the Office Action refers to the reference as U.S. Patent No. 47,481,732. It is assumed that this is a typographical error and that the Examiner is in fact citing U.S. Patent No. 4,748,173.



According to the claimed process, a solution or suspension comprising mycophenolate mofetil and process by-products is treated with a primary or secondary amine and the mycophenolate mofetil of formula I is then isolated from the solution or suspension to provide purified mycophenolate mofetil. The by-products being removed by this process include dimers having the following structure:



II

This structure is designated as formula II in Applicants' specification.

This process is not suggested in the Nelson disclosure. Nelson says nothing about separating any dimer by-product according to Applicants' process. Nelson certainly does not

U.S. Application No. 10/570,641

suggest that a dimer by-product of any kind may be present with any solution or suspension of the mycophenolate mofetil, much less that the same would have been removed by treatment with a primary or secondary amine followed by isolation of the mycophenolate mofetil in purified form.

Therefore, independent Claim 1 (and each of its dependent claims) patentably distinguishes over the Nelson reference for at least this reason.

In addition, the Applicants have added new Claim 26 to the case which depends from Claim 1 and further specifies that the maximum amount of dimer by-products in the purified mycophenolate mofetil is 0.1% (area percent HPLC). Nothing in Nelson suggests the presence of any dimer by-product in a purified form of the compound claimed by Applicants, much less an amount less than 0.1%. Nor is there anything in Nelson to suggest the presence of any dimer impurities in the particular materials being processed. It would be pure speculation and conjecture to assert that dimer by-products would have been present in any amount. Thus, new Claim 26, like Claim 1, patentably distinguishes over the Nelson reference for this additional reason as well.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event that this response is not timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other fees which may be due with respect to this response, may be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: /Mark S. Graham/

Mark S. Graham
Registration No. 32,355

Date: July 29, 2010
P.O. Box 1871
Knoxville, Tennessee 37901
(865) 546-4305
E-Filing